# 510(k) Summary of Safety and Effectiveness

DEC 2 8 2010

***This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.***

## Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

## Submitter name, Address, and Contact

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Contact: Bernice Lin, Ph.D.
VP Operations

## Device Name and Classification

Classification Name: Enzyme Immunoassay, Amphetamines
Class II, DKZ (91 Toxicology),
21 CFR 862.3100

Thin Layer Chromatography, Methamphetamine
Class II, DJC (91 Toxicology),
21 CFR 862.3610

Amphetamines Calibrators,
Class II, DLJ (91 Toxicology),
21 CFR 862.3200

Amphetamines Controls,
Class I, LAS (91 Toxicology),
21 CFR 862.3280

Common Name: Homogeneous Amphetamines Enzyme Immunoassay

Proprietary Name: LZI Amphetamines 500 Enzyme Immunoassay,
LZI Amphetamines 500 Drugs of Abuse (DAU) Calibrators
LZI Amphetamines 500 Drugs of Abuse (DAU) Controls

## Legally Marketed Predicate Device(s)

The LZI Amphetamines 500 Enzyme Immunoassay (EIA) is substantially equivalent to the Lin-Zhi International, Inc. Amphetamines Enzyme Immunoassay, Calibrators and Controls for Hitachi 717 Systems (k020395) manufactured by Lin-Zhi International, Inc. The LZI Amphetamines 500 Enzyme Immunoassay is identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance.

## Device Description

The LZI Amphetamines 500 assay is a homogeneous enzyme immunoassay with ready-to-use liquid reagent. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent. Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, amphetamines-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when free drug is present in the sample, antibody would bind to free drug, the unbound amphetamines-labeled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at 340 nm.

The LZI Amphetamines 500 Enzyme Immunoassay is a kit comprised of two reagents, an $R_1$ and $R_2$ which are bottled separately but sold together within the kit.

The $R_1$ solution contains two mouse monoclonal anti-amphetamines antibodies, glucose-6-phosphate (G6P) nicotinamide adenine dinucleotide (NAD), stabilizers, and sodium azide (0.09%) as a preservative. The $R_2$ solution contains glucose-6-phosphate dehydrogenase (G6PDH) labeled with amphetamines in buffer with sodium azide (0.09%) as preservative.

The LZI Amphetamines 500 Enzyme Immunoassay calibrators and controls contain 0, 250, 375, 500, 625, 1000, or 2000 ng/mL of d-methamphetamine in human urine with sodium azide (0.09%) as preservative. These five calibrators and two controls are sold as individual bottles.

## Intended Use

The LZI Amphetamines 500 Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of amphetamine and methamphetamine in human urine, at a cutoff value of 500 ng/mL when calibrated with d-methamphetamine. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

The LZI Amphetamines 500 Drugs of Abuse (DAU) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Amphetamines Enzyme Immunoassay.

The LZI Amphetamines 500 Drugs of Abuse (DAU) Controls are for use as assayed quality control materials to monitor the precision of the LZI Amphetamines 500 Enzyme Immunoassay.

***The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.***

## Comparison to Predicate Device

The LZI Amphetamines 500 Enzyme Immunoassay is substantially equivalent to the Lin-Zhi International, Inc. Amphetamines Enzyme Immunoassay, Calibrators and Controls for Hitachi 717 Systems cleared by the FDA under the premarket notification k020395 for its stated intended use.

The following table compares LZI's Amphetamines 500 Enzyme Immunoassay with the predicate device.

| **Device Characteristics** | **Subject Device (k102210)** LZI Amphetamines 500 Enzyme Immunoassay | **Predicate Device (k020395)** LZI Amphetamines Enzyme Immunoassay |
|---|---|---|
| **Intended Use** | The LZI Amphetamines 500 Enzyme Immunoassay, when used in conjunction with Hitachi 717 automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of amphetamine and methamphetamine in human urine, at a cutoff value of 500 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers.<br><br>***This assay provides a rapid screening procedure for determining the presence of Amphetamines in urine. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.*** | The LZI Amphetamines Enzyme Immunoassay, when used in conjunction with Hitachi 717 automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of Amphetamines in human urine, at a cutoff value of 1000 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers.<br><br>***This assay provides a rapid screening procedure for determining the presence of Amphetamines in urine. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.*** |
| **Analyte** | d-methamphetamine and d-amphetamine | Amphetamines |
| **Cutoff** | 500 ng/ml | 1000 ng/mL |
| **Matrix** | Urine | Urine |
| **Calibrators Level** | 5 Levels<br>(0, 250, 500, 1000, 2000 ng/mL) | 5 Levels<br>(0, 500, 1000, 1500, 2000 ng/mL) |
| **Controls Level** | 2 Levels<br>(375 ng/mL, 625 ng/mL) | 2 Levels<br>(750 ng/mL, 1250 ng/mL) |
| **Storage** | 2-8 °C until expiration date | 2-8 °C until expiration date |

# Performance Characteristics Summary:

**Hitachi 717 Analyzer**

## Precision: d-methamphetamine

**Precision: Semi-Quantitative, ng/mL**

| N=88 (ng/mL) | Within Run | | | Total Precision | | |
|---|---|---|---|---|---|---|
| | Mean | SD | % CV | Mean | SD | % CV |
| 0 ng/mL | 5.6 | 5.3 | 116.6 % | 5.6 | 7.5 | 132.1% |
| 125 ng/mL | 128.3 | 6.4 | 5.0 % | 128.3 | 8.4 | 6.6% |
| 250 ng/mL | 252.9 | 6.1 | 2.4 % | 252.9 | 9.1 | 3.6% |
| 375 ng/mL | 369.6 | 11.4 | 3.1 % | 369.6 | 14.6 | 4.0% |
| 500 ng/mL | 489.9 | 11.7 | 2.4 % | 489.9 | 15.9 | 3.2% |
| 625 ng/mL | 605.3 | 17.6 | 2.9 % | 605.3 | 19.3 | 3.2% |
| 750 ng/mL | 746.5 | 16.3 | 2.2 % | 746.5 | 18.9 | 2.5% |
| 875 ng/mL | 867.7 | 22.9 | 2.6 % | 867.7 | 25.6 | 3.0% |
| 1000 ng/mL | 1024.2 | 34.0 | 3.3 % | 1024.2 | 41.8 | 4.1% |

**Semi-Quantitative Precision Analysis Summary:** Qualitative Results

| N=88 (ng/mL) | Within Run | | Total Precision | |
|---|---|---|---|---|
| | Mean | Qualitative Response | Mean | Qualitative Response |
| 0 ng/mL | 5.6 | - | 5.6 | - |
| 125 ng/mL | 128.3 | - | 128.3 | - |
| 250 ng/mL | 252.9 | - | 252.9 | - |
| 375 ng/mL | 369.6 | - | 369.6 | - |
| 500 ng/mL | 489.9 | - | 489.9 | - |
| 625 ng/mL | 605.3 | + | 605.3 | + |
| 750 ng/mL | 746.5 | + | 746.5 | + |
| 875 ng/mL | 867.7 | + | 867.7 | + |
| 1000 ng/mL | 1024.2 | + | 1024.2 | + |

**Semi-Quantitative Positive/Negative Results:**

| 500 ng/mL Cutoff Result: | | Within Run | | Total Precision | |
|---|---|---|---|---|---|
| Sample Concentration | % of Cutoff | Number of Determination | Immunoassay Result | Number of Determination | Immunoassay Result |
| 0 ng/mL | -100.0% | 22 | 22 Negative | 88 | 88 Negative |
| 125 ng/mL | -75.0% | 22 | 22 Negative | 88 | 88 Negative |
| 250 ng/mL | -50.0% | 22 | 22 Negative | 88 | 88 Negative |
| 375 ng/mL | -25.0% | 22 | 22 Negative | 88 | 88 Negative |
| 500 ng/mL | 100.0% | 22 | 3 Pos/19 Neg | 88 | 18 Pos/70 Neg |
| 625 ng/mL | +25.0% | 22 | 22 Positive | 88 | 88 Positive |
| 750 ng/mL | +50.0% | 22 | 22 Positive | 88 | 88 Positive |
| 875 ng/mL | +75.0% | 22 | 22 Positive | 88 | 88 Positive |
| 1000 ng/mL | +100.0% | 22 | 22 Positive | 88 | 88 Positive |

**Precision: Qualitative, mA/min**

| N=88 | Within Run | | | Total Precision | | |
|---|---|---|---|---|---|---|
| (mA/min) | Mean | SD | % CV | Mean | SD | % CV |
| 0 ng/mL | 273.5 | 2.8 | 1.0 % | 273.5 | 3.4 | 1.2 % |
| 125 ng/mL | 314.5 | 2.2 | 0.7 % | 314.5 | 3.0 | 0.9 % |
| 250 ng/mL | 359.0 | 2.2 | 0.6 % | 359.0 | 3.4 | 0.9 % |
| 375 ng/mL | 398.2 | 3.0 | 0.8 % | 398.2 | 4.1 | 1.0 % |
| 500 ng/mL | 431.3 | 3.0 | 0.7 % | 431.3 | 4.3 | 1.0 % |
| 625 ng/mL | 459.6 | 3.8 | 0.8 % | 459.6 | 5.2 | 1.1 % |
| 750 ng/mL | 489.2 | 3.9 | 0.8 % | 489.2 | 5.4 | 1.1 % |
| 875 ng/mL | 509.7 | 4.1 | 0.8 % | 509.7 | 5.1 | 1.0 % |
| 1000 ng/mL | 533.1 | 3.7 | 0.7 % | 533.1 | 4.8 | 0.9 % |

**Qualitative Positive/Negative Results:**

| 500 ng/mL Cutoff Result: | | Within Run | | Total Precision | |
|---|---|---|---|---|---|
| Sample Concentration | % of Cutoff | Number of Determination | Immunoassay Result | Number of Determination | Immunoassay Result |
| 0 ng/mL | -100.0% | 22 | 22 Negative | 88 | 88 Negative |
| 125 ng/mL | -75.0% | 22 | 22 Negative | 88 | 88 Negative |
| 250 ng/mL | -50.0% | 22 | 22 Negative | 88 | 88 Negative |
| 375 ng/mL | -25.0% | 22 | 22 Negative | 88 | 88 Negative |
| 500 ng/mL | 100.0% | 22 | 13 Pos/9 Neg | 88 | 54Pos/34 Neg |
| 625 ng/mL | +25.0% | 22 | 22 Positive | 88 | 88 Positive |
| 750 ng/mL | +50.0% | 22 | 22 Positive | 88 | 88 Positive |
| 875 ng/mL | +75.0% | 22 | 22 Positive | 88 | 88 Positive |
| 1000 ng/mL | +100.0% | 22 | 22 Positive | 88 | 88 Positive |

# Performance Characteristics Summary: continued

**Hitachi 717 Analyzer**

## Precision: d-amphetamine

**Precision: Semi-Quantitative, ng/mL**

| N=88 (ng/mL) | Within Run | | | Total Precision | | |
|---|---|---|---|---|---|---|
| | Mean | SD | % CV | Mean | SD | % CV |
| 0 ng/mL | 18.2 | 15.1 | 77.6% | 18.2 | 17.8 | 98.1% |
| 125 ng/mL | 165.5 | 10.1 | 6.1% | 165.5 | 14.3 | 8.6% |
| 250 ng/mL | 297.4 | 8.1 | 2.7% | 297.4 | 14.0 | 4.7% |
| 375 ng/mL | 409.0 | 8.2 | 2.0% | 409.0 | 15.7 | 3.8% |
| 500 ng/mL | 529.9 | 13.7 | 2.6% | 529.9 | 17.3 | 3.3% |
| 625 ng/mL | 631.3 | 10.6 | 1.7% | 631.3 | 18.5 | 2.9% |
| 750 ng/mL | 714.0 | 19.0 | 2.7% | 714.0 | 23.0 | 3.2% |
| 875 ng/mL | 809.1 | 15.4 | 1.9% | 809.1 | 20.7 | 2.6% |
| 1000 ng/mL | 910.6 | 20.2 | 2.2% | 910.6 | 26.6 | 2.9% |

**Semi-Quantitative Precision Analysis Summary:** Qualitative Results

| N=88 (ng/mL) | Within Run | | Total Precision | |
|---|---|---|---|---|
| | Mean | Qualitative Response | Mean | Qualitative Response |
| 0 ng/mL | 18.2 | - | 18.2 | - |
| 125 ng/mL | 165.5 | - | 165.5 | - |
| 250 ng/mL | 297.4 | - | 297.4 | - |
| 375 ng/mL | 409.0 | - | 409.0 | - |
| 500 ng/mL | 529.9 | + | 529.9 | + |
| 625 ng/mL | 631.3 | + | 631.3 | + |
| 750 ng/mL | 714.0 | + | 714.0 | + |
| 875 ng/mL | 809.1 | + | 809.1 | + |
| 1000 ng/mL | 910.6 | + | 910.6 | + |

**Semi-Quantitative Positive/Negative Results:**

| 500 ng/mL Cutoff Result: | | Within Run | | Total Precision | |
|---|---|---|---|---|---|
| Sample Concentration | % of Cutoff | Number of Determination | Immunoassay Result | Number of Determination | Immunoassay Result |
| 0 ng/mL | -100.0% | 22 | 22 Negative | 88 | 88 Negative |
| 125 ng/mL | -75.0% | 22 | 22 Negative | 88 | 88 Negative |
| 250 ng/mL | -50.0% | 22 | 22 Negative | 88 | 88 Negative |
| 375 ng/mL | -25.0% | 22 | 22 Negative | 88 | 88 Negative |
| 500 ng/mL | 100.0% | 22 | 22 Positive | 88 | 83 Pos/5 Neg |
| 625 ng/mL | +25.0% | 22 | 22 Positive | 88 | 88 Positive |
| 750 ng/mL | +50.0% | 22 | 22 Positive | 88 | 88 Positive |
| 875 ng/mL | +75.0% | 22 | 22 Positive | 88 | 88 Positive |
| 1000 ng/mL | +100.0% | 22 | 22 Positive | 88 | 88 Positive |

**Precision: Qualitative, mA/min**

| N=88 (mA/min) | Within Run | | | Total Precision | | |
|---|---|---|---|---|---|---|
| | Mean | SD | % CV | Mean | SD | % CV |
| 0 ng/mL | 330.4 | 2.5 | 0.8% | 330.4 | 3.2 | 1.0% |
| 125 ng/mL | 362.6 | 1.7 | 0.5% | 362.6 | 2.7 | 0.8% |
| 250 ng/mL | 400.5 | 2.6 | 0.6% | 400.5 | 3.5 | 0.9% |
| 375 ng/mL | 429.9 | 2.3 | 0.5% | 429.9 | 3.4 | 0.8% |
| 500 ng/mL | 458.9 | 4.3 | 0.9% | 458.9 | 4.9 | 1.1% |
| 625 ng/mL | 484.6 | 2.3 | 0.5% | 484.6 | 3.6 | 0.7% |
| 750 ng/mL | 498.9 | 3.2 | 0.6% | 498.9 | 4.4 | 0.9% |
| 875 ng/mL | 515.5 | 2.8 | 0.5% | 515.5 | 4.1 | 0.8% |
| 1000 ng/mL | 533.2 | 2.6 | 0.5% | 533.2 | 4.4 | 0.8% |

**Qualitative Positive/Negative Results:**

| 500 ng/mL Cutoff Result: | | Within Run | | Total Precision | |
|---|---|---|---|---|---|
| Sample Concentration | % of Cutoff | Number of Determination | Immunoassay Result | Number of Determination | Immunoassay Result |
| 0 ng/mL | -100.0% | 22 | 22 Negative | 88 | 88 Negative |
| 125 ng/mL | -75.0% | 22 | 22 Negative | 88 | 88 Negative |
| 250 ng/mL | -50.0% | 22 | 22 Negative | 88 | 88 Negative |
| 375 ng/mL | -25.0% | 22 | 22 Negative | 88 | 88 Negative |
| 500 ng/mL | 100.0% | 22 | 15 Pos/7 Neg | 88 | 48 Pos/40 Neg |
| 625 ng/mL | +25.0% | 22 | 22 Positive | 88 | 88 Positive |
| 750 ng/mL | +50.0% | 22 | 22 Positive | 88 | 88 Positive |
| 875 ng/mL | +75.0% | 22 | 22 Positive | 88 | 88 Positive |
| 1000 ng/mL | +100.0% | 22 | 22 Positive | 88 | 88 Positive |

## Performance Characteristics Summary: continued
**Hitachi 717 Analyzer**

### Limit of Detection: d-methamphetamine and d-amphetamine
The lowest concentration that can be differentiated from the negative urine with 95% confidence is determined as 50 ng/mL for both d-methamphetamine and d-amphetamine.

### Linearity: d-methamphetamine
Hitachi 717 Instrument: 0 - 2000 ng/mL
When comparing the result (y) and target (x) value, using the least squares regression technique, the regression equation and correlation are as follow:
$y = 0.9717x + 5.7341$, $r^2 = 0.9971$

### Linearity: d-amphetamine
Hitachi 717 Instrument: 0 - 2000 ng/mL
When comparing the result (y) and target (x) value, using the least squares regression technique, the regression equation and correlation are as follow:
$y = 0.9447x + 24.34$, $r^2 = 0.9978$

### Method Comparison - Clinical Samples : d-methamphetamine
From a total of eighty-six (86) clinical unaltered samples: 500 ng/mL Cutoff
Semi-Quantitative Data: 100% agreement with positive, 67.4% agreement with negative samples
Qualitative Data: 100% agreement with positive, 69.8% agreement with negative samples

### Method Comparison - Clinical Samples : d-amphetamine
From a total of one-hundred and eleven (111) clinical unaltered samples: 500 ng/mL Cutoff
Semi-Quantitative Data: 97.8% agreement with positive, 100% agreement with negative samples
Qualitative Data: 96.4% agreement with positive, 100% agreement with negative samples

### Endogenous Compound Interference and Specificity - Cross-Reactivity: d-methamphetamine and d-amphetamine
This assay showed cross-reactivity with four compounds: PMA, MDA, MDMA, and MDEA due to their similar chemical structures. No significant undesired cross reactants or endogenous substance interference was observed for both d-methamphetamine and d-amphetamine otherwise.

## Summary:
The information provided in this pre-market notification demonstrates that the LZI Amphetamines 500 Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device for its general intended use. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available predicate device as confirmed by chromatography/mass spectrometry (GC/MS or LC/MS), an independent analytical method. The information supplied in this pre-market notification provides reasonable assurance that the LZI 500 Amphetamines Enzyme Immunoassay is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Lin-Zhi International, Inc.
c/o Dr. Bernice Lin
VP Operations
670 Almanor Avenue
Sunnyvale, CA 94085

DEC 2 8 2010

Re: k102210
Trade Name: LZI Amphetamines 500 Homogeneous Enzyme Immunoassay, Amphetamines 500 Drugs of Abuse Calibrators and Controls
Regulation Number: 21 CFR §862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DJC, DLJ, LAS
Dated: December 17 2010
Received: December 17, 2010

Dear Dr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Premarket Notification

## Indications for Use Statement

DEC 2 8 2010

**510(k) Number (if known): k102210**

**Device Name: Amphetamines 500 Enzyme Immunoassay**
**Amphetamines 500 Calibrators and Controls**

**Indications for Use:**

The LZI Amphetamines 500 Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of amphetamine and methamphetamine in human urine, at a cutoff value of 500 ng/mL when calibrated with d-methamphetamine. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

The LZI Amphetamines 500 Drugs of Abuse (DAU) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the LZI Amphetamines Enzyme Immunoassay.

The LZI Amphetamines 500 Drugs of Abuse (DAU) Controls are for use as assayed quality control materials to monitor the precision of the LZI Amphetamines 500 Enzyme Immunoassay.

***The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive***

**Prescription Use** __√__ **AND/OR** **Over-The-Counter Use** _____
**(Part 21 CFR 801 Subpart D)** **(21 CFR 807 Subpart C)**

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**Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)**
**(Per 21 CFR 801.109)**

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K102210